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April 13, 1999

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Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane Room 1061
Rockville, MD 20857

To the Food and Drug Administration:


I strongly oppose the Draft MOU being proposed at this time. In particular, I object to the definition of "inordinate amount" which restricts the availability and the right to obtain necessary, compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

I have systemic lupus which can be exacerbated by a very lengthy list of prescription medications. Having developed significant hypertension, I spoke with my cardiologist about the difficulties of a lupus patient taking antihypertensives: many of the antihypertensives are contraindicated for lupus patients. I tried Lotensin, one of the most common and effective antihypertensives, beginning with a half of the usual starting dose. Two days later, I developed a high fever, chills and pain and had to go to the hospital with acute pancreatitis—one of the known side effects of this drug. I have now begun to take Clonidine but began with 1/10 the usual starting dose. This prescription had to be compounded for me at one of the special compounding pharmacies. I have now been able over a period of weeks to build up slowly to a half dose of Clonidine and have begun to see a lowering of my blood pressure. I have been able to weather the various side effects of this drug as I could take appropriate measures by consulting with my physicians about how to manage these effects over a period of time. This would not be possible if I had to start at a higher dose.

This is not the first or only time I have used compounding pharmacies. For many years I had an acute inflammation in my eyes that required high doses of steroid drops several times each day. I was allergic to the preservatives in this preparation. Without a compounding pharmacy, I should likely have suffered significant loss of vision as I could not have tolerated the required medication.

There are few compounding pharmacies. Gone are the days when every pharmacist had a mortar and pestle and could prepare the appropriate medication. The pharmacy I and my physicians rely on is the College Pharmacy in Colorado. If your memorandum is approved, people like me will not have access to necessary medication. I strongly urge you not to approve or adopt the MOU currently proposed.

Very truly yours,



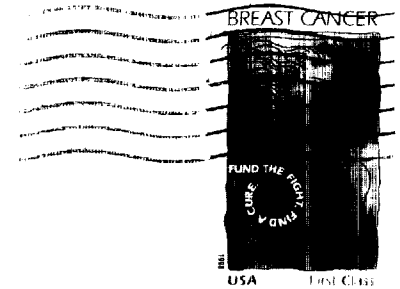
Susan L. Feldman

CC: Representative Nancy Pelosi
House of Representatives

98N-1265

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